

## **REMARKS**

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed March 19, 2008. Currently, claims 1-19 remain pending. Claims 1-19 have been rejected. In this amendment, claim 1 has been amended. Favorable consideration of the following remarks is respectfully requested.

### ***Claim Amendments***

In this Amendment, Applicants have amended claim 1 to correct the inadvertent omission of the term “sheath”. In particular, Applicants amended the phrase “the retractable co-axially disposed around at least the shaft distal region” to “the retractable sheath co-axially disposed around at least the shaft distal region”. As such, no new matter has been entered.

### ***Claim Rejections under 35 U.S.C. § 103***

In paragraph 2 of the Final Office Action, claims 1-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenker et al. (EP 0 696 447 A2) in view of Thompson et al. (U.S. Patent No. 5,957,974). After careful review, Applicants must respectfully traverse this rejection.

Turning to claim 1, which recites:

1. A self-expanding stent delivery assembly comprising:
  - a shaft having a distal region and a longitudinal axis;
  - a retractable sheath having a proximal end and a distal end, the retractable sheath co-axially disposed around at least the shaft distal region;
  - a stent disposed co-axially between the shaft and the retractable sheath in the distal region;
  - a stop member coupled to the shaft and positioned proximally of the stent; and
  - a tubular tapered tip affixed to the retractable sheath distal end, the tubular tapered tip having an elongate region predisposed to fracturing.

Nowhere does the combination of Lenker et al. and Thompson et al. teach or suggest “the tubular tapered tip having an elongate region predisposed to fracturing”, as recited in claim 1.

In the Final Office Action, the Examiner appears to rely on Figure 31 of Lenker et al. as teaching or suggesting the tubular tapered tip having an elongate region predisposed to fracturing. In particular, the Examiner appears to be relying on elements 482 and 484 of Figure

31. Applicants must respectfully disagree and assert that Lenker et al. fail to teach, suggest, or disclose these structural features.

For illustrative purposes, Figure 31 is reproduced below.

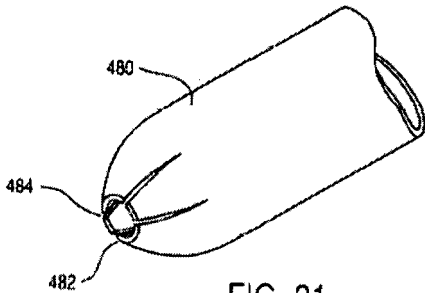


FIG. 31

In addition, with regards to Figure 31, Lenker et al. recites:

Referring now to Fig. 31, an alternative cover 480 provides an atraumatic distal end 482 with a reduced nosecone diameter, or, alternatively, no nosecone at the distal end of core shaft 444. Atraumatic cover 480 includes a series of splits 484 to allow the distal tip of atraumatic cover 480 to open during deployment of prosthesis 10.

Lenker et al. at column 21, lines 28-34 (emphasis added). Thus, the cover 480 as taught by Lenker et al. presumably includes a plurality of slits 484 through the cover 480. Applicants assert that the slits or cuts 484 of the cover 480 of Lenker et al. do not teach or suggest the “elongate region predisposed to fracturing” as currently claimed. The claimed “elongate region predisposed to fracturing” describes a region of the claimed tapered tip which is susceptible to being broken or separated, yet is not broken or separated prior to deployment of the stent. Applicants note that the present description describes three possible regions predisposed to fracturing at lines 3-8 of page 8. These three examples of an elongate region predisposed to fracturing are also claimed in claims 3 through 5, discussed below. The present description states:

In an illustrative embodiment, the elongate region predisposed to fracturing 90 can be a line of perforations that extend through a portion of or through the entire tubular tip 36 wall thickness. The elongate region predisposed to fracturing 90 can be a score line that extends through a portion of the tubular tip 36 wall thickness where the wall thickness along the score line 90 is less than the thickness along the remaining tubular tip 36 wall. Alternatively or in addition, the elongate region predisposed to fracturing 90 can be material having a tensile strength that is less than the tensile strength of the remaining tubular tip 36.

As can be clearly seen, the claimed elongate region predisposed to fracturing is a region of material which holds adjacent portions of the tip together prior to being fractured, yet is a region which is susceptible to being broken to separate adjacent portions of the tip at a determined time.

To the contrary, as disclosed by Lenker et al., the slits 484 cut through the cover 480 are not predisposed to fracturing as the slits 484 indicate that the portions of the cover 480 are already separated by the slits 484 into discrete sections and no further fracturing of the slits 484 is contemplated. The slits 484 are an absence of material, not a region of material which holds adjacent portions of the cover together prior to being fractured. Because the cover 480 has already been split, no "fracturing" is taught or contemplated by Lenker et al.

In the Advisory Action mailed August 7, 2007, the Examiner asserted that the slits of Lenker et al. are clearly equivalent to "predisposed to fracturing" due to the definition of "fracture", which includes the entry, "a break, breach, or split". The Examiner is ignoring a key portion of the claim language, i.e., "predisposed to", and is interpreting the claim as reciting a region that is fractured. Applicants also remind the Examiner that "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (See MPEP § 2143.03). As such, ignoring any word in a claim in judging patentability is error. Claim 1 recites "an elongate region predisposed to fracturing". The definition of "predispose" according to the Merriam-Webster online dictionary is:

- 1 : to dispose in advance <a good teacher *predisposes* children to learn>
- 2 : to make susceptible <malnutrition *predisposes* one to disease>
- intransitive verb : to bring about susceptibility

Emphasis added. The claimed phrase, "predisposed to fracturing", thus cannot be seen to mean already split, as suggested by the Examiner.

Additionally, Applicants remind the Examiner that § 2141 of the MPEP states:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396.

In the Final Office Action, the Examiner fails to provide any articulated reasons with some rational underpinning to support the assertion that the slits of Lenker et al. teach or suggest the claimed “elongate region predisposed to fracturing”. Therefore, for at least these reasons, claim 1 is believed to be patentable over Lenker et al. in view of Thompson et al. For similar reasons and others, claims 2-10, which depend from claim 1 and include additional limitations, are believed to be patentable over the combination of Lenker et al. and Thompson et al.

Turning to claim 3, which recites:

3. The self-expanding stent delivery assembly according to claim 1, wherein the elongate region predisposed to fracturing is a line of perforations.

Nowhere does the combination of Lenker et al. and Thompson et al. teach or suggest “wherein the elongate region predisposed to fracturing is a line of perforations”, as recited in claim 3. Furthermore, nowhere does the Examiner cite any portion of Lenker et al. or Thompson et al. as teaching or suggesting this limitation. Therefore, for at least this reason, claim 3, which depends from claim 1, is believed to be patentable over the combination of Lenker et al. and Thompson et al.

Turning to claim 4, which recites:

4. The self-expanding stent delivery assembly according to claim 1, wherein the tubular tip has a first thickness and the elongate region predisposed to fracturing has a second thickness that is less than the first thickness.

Nowhere does the combination of Lenker et al. and Thompson et al. teach or suggest “wherein the tubular tip has a first thickness and the elongate region predisposed to fracturing has a second thickness that is less than the first thickness”, as recited in claim 4. Furthermore, nowhere does the Examiner cite any portion of Lenker et al. or Thompson et al. as teaching or suggesting this limitation. Therefore, for at least this reason, claim 4, which depends from claim 1, is believed to be patentable over the combination of Lenker et al. and Thompson et al.

Turning to claim 5, which recites:

5. The self-expanding stent delivery assembly according to claim 1, wherein the tubular tip is formed of a first material having a first tensile strength and the elongate region predisposed to fracturing is formed of a second material having a second tensile strength that is less than the first tensile strength.

Nowhere does the combination of Lenker et al. and Thompson et al. teach or suggest “wherein the tubular tip is formed of a first material having a first tensile strength and the elongate region predisposed to fracturing is formed of a second material having a second tensile strength that is less than the first tensile strength”, as recited in claim 5. Furthermore, nowhere does the Examiner cite any portion of Lenker et al. or Thompson et al. as teaching or suggesting this limitation. Therefore, for at least this reason, claim 5, which depends from claim 1, is believed to be patentable over the combination of Lenker et al. and Thompson et al.

Turning to claim 11, which recites:

11. A method of delivering a self-expanding stent comprising:  
placing a stent delivery device at a target site, the stent delivery device comprising:  
a shaft having a distal region and a longitudinal axis;  
a retractable sheath having a proximal end and a distal end, the retractable sheath co-axially disposed around the shaft distal region;  
a stent disposed co-axially between the shaft and the retractable sheath in the distal region;  
a stop member coupled to the shaft and positioned proximally of the stent;  
and  
a tubular tapered tip affixed to the retractable sheath distal end, the tubular tapered tip having an elongate region predisposed to fracturing;  
deploying the stent at the target site by retracting the retractable sheath or advancing the stent and fracturing the elongate region predisposed to fracturing;  
and  
removing the stent delivery device from the target site.

As discussed previously, nowhere does the combination of Lenker et al. and Thompson et al. teach or suggest “the tubular tapered tip having an elongate region predisposed to fracturing”, as recited in claim 11. Therefore, for at least this reason, claim 11 is believed to be patentable over the combination of Lenker et al. and Thompson et al. For similar reasons and others, claims 12-19, which depend from claim 11 and include additional limitations, are believed to be patentable over the combination of Lenker et al. and Thompson et al.

Additionally, Applicants remind the Examiner of the obligation to clearly state the grounds for rejecting each of the claims in every Office Action. (See M.P.E.P. §707.07(d)). If the Examiner wishes to renew the rejection of these claims, Applicants respectfully request the Examiner clearly indicate what portions of Lenker et al. or Thompson et al. teach or suggest the claimed limitations and provide Applicants an opportunity to properly respond. (See M.P.E.P.

§707.07(f)). Accordingly, Applicants respectfully request that the Examiner issue a new **non-final Office Action**.

**Conclusion**

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

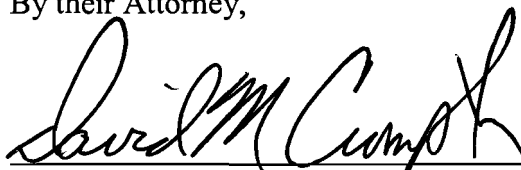
Respectfully submitted,

William S. Henry et al.

By their Attorney,

Date: \_\_\_\_\_

6/12/08



David M. Crompton, Reg. No. 36,772  
CROMPTON, SEAGER & ZUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, MN 55403-2420  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349